

FREQUENTLY ASKED QUESTIONS ABOUT THE PUBLIC HEALTH GOAL FOR PERCHLORATE

In March 2004, as mandated by state law and court order, the Office of Environmental Health Hazard Assessment (OEHHA) published a final Public Health Goal (PHG) of 6 parts per billion (ppb) for perchlorate, an ingredient in rocket fuel and other industrial products that has been found in some California drinking water supplies. This fact sheet addresses specific questions concerning this PHG. Additional information can be found on OEHHA's Web site at www.oehha.ca.gov.

1. What is a PHG?

A: A PHG, or public health goal, is a level of a contaminant in drinking water that does not pose a significant short-term or long-term health risk. A PHG is not a regulatory requirement. Instead, it is a goal for drinking water that California's public water suppliers and regulators should strive to meet if it is feasible to do so. State law requires OEHHA to develop PHGs for regulated drinking water contaminants. A state law enacted in 2002 (SB 1822 by Senator Byron Sher) created a legal mandate for OEHHA to develop a PHG for perchlorate.

2. How are PHGs used in developing California's regulatory drinking water standards?

A: The California Department of Health Services (DHS) regulates public drinking water suppliers and sets California's regulatory drinking water standards, officially known as Maximum Contaminant Levels (MCLs). State law requires DHS to set each MCL as close to the corresponding PHG as is economically and technically feasible, placing primary emphasis on the protection of public health. DHS can set the MCL above the level of the PHG if it determines that the economic impact on water suppliers or consumers of reducing a contaminant to the PHG level would be excessive compared to the reduction in estimated health risk, or if current testing or treatment technologies are not adequate to ensure drinking water contamination levels would be at or below the PHG. State law prohibits OEHHA from considering economic issues when it develops a PHG.

3. What are the health effects of perchlorate?

A: Perchlorate can limit the uptake of iodide, an essential nutrient, by the thyroid gland. Research has shown that reduced levels of iodide in the thyroid can disrupt thyroid hormones that regulate metabolism and growth. Short-term fluctuations in thyroid hormone levels are normal and the body has a certain capacity to cope and adjust for these small changes. Continuous thyroid disruption, however, may cause an imbalance, especially when a body is already under stress (e.g., due to iodine deficiency or pregnancy). Certain populations are particularly susceptible, such as pregnant women and infants, to adverse health effects when this occurs. Impairment of

thyroid function in expectant mothers may affect the fetus and newborn and could result in delayed development and decreased learning capability. Although research has found that perchlorate at higher levels can limit the uptake of iodide by the thyroid gland in humans, these studies have not directly measured the impact of perchlorate on human metabolism and growth. However, adverse effects of perchlorate on thyroid hormones and development of fetal brain have been observed in rats.

4. What is the history of efforts to develop perchlorate guidelines for drinking water?

A: Efforts to evaluate perchlorate for purposes of establishing goals and regulatory standards extend back more than a decade. In 1992, the U.S. Environmental Protection Agency (U.S. EPA) published a provisional "reference dose" for perchlorate exposure that would not be expected to pose a health threat. This reference dose was equivalent to a drinking water concentration of 4 to 18 ppb. In 1997, DHS set a state "action level" (an advisory level for contaminants for which there is no regulatory standard) of 18 ppb for perchlorate. In 1998, OEHHA began developing a PHG for perchlorate. In 2002, U.S. EPA released a revised draft reference dose (currently under review by the National Academies of Sciences) and DHS revised the state action level to 4 ppb. Also in 2002, the California Legislature passed a bill to require OEHHA to establish a PHG and DHS to establish a drinking water standard or MCL for perchlorate. Later in the year, OEHHA released a draft document proposing the PHG be within the range of 2 to 6 ppb. In 2004, OEHHA published a final PHG of 6 ppb. DHS has aligned the action level to the 6 ppb PHG and will use the PHG as the health basis for developing a regulatory drinking water standard, as explained in the answer to Question No. 2.

5. Before the PHG was published, how has the State protected drinking water from perchlorate contamination?

A: When results of early findings on perchlorate in drinking water were released in 1997, the DHS established a perchlorate "action level" (health-based advisory level) at 18 ppb using a federal U.S. EPA risk assessment. In 2002, DHS lowered the action level to 4 ppb in response to EPA's revised draft risk assessment on perchlorate. Four parts per billion was the lower value of the range and the limit of detection for drinking water. As a result, most water systems with contaminated sources have either closed their sources or taken measures to reduce or remove perchlorate. All affected water systems have informed their customers of the contamination.

Because the OEHHA PHG represents the most complete and thorough risk assessment to date, and because DHS is required to set the drinking water standard as close as possible to the PHG as is feasible, DHS has aligned the action level to the 6 ppb PHG.

6. How rigorously was OEHHA's PHG for perchlorate reviewed, and was there opportunity for public input?

A: The draft PHG for perchlorate was more extensively reviewed than any of the other 69 PHGs that OEHHA has developed to date. Drafts of OEHHA's PHG document for perchlorate were submitted to the University of California for two separate rounds of external scientific peer review. OEHHA's normal process only calls for one round of peer review by the University. The U.S. EPA also peer reviewed the document. OEHHA also held two public comment periods and a public workshop on the draft PHG documents. OEHHA began development of the perchlorate PHG in 1998. It is the product of almost six years of assessments and reviews.

7. What is the major scientific question surrounding OEHHA's PHG?

A: The major scientific question concerns the amount of perchlorate exposure that can affect human health outcomes. Research has shown that reduced levels of iodide in the thyroid can disrupt thyroid hormones that regulate metabolism and growth. Certain populations are particularly susceptible, such as pregnant women and infants, to adverse health effects when this occurs. Although research has found that perchlorate at higher levels can limit the uptake of iodide by the thyroid gland in humans, these studies have not directly measured the impact of perchlorate on human metabolism and growth. However, adverse effects of perchlorate on thyroid hormones and development of fetal brain have been observed in rats. State and industry scientists agree that a 2002 study of perchlorate by Greer, et. al. provided good data on the effects of perchlorate on healthy adults. In this study, human volunteers were given perchlorate in drinking water over a 14-day period. OEHHA took the Greer study's data on healthy adults and, using a well-accepted scientific method, added margins of safety to calculate a PHG that protects pregnant women and infants. There are a number of different ways to calculate margins of safety, and therefore it is not surprising that different scientists would recommend different margins of safety under these circumstances. OEHHA scientists followed requirements in state law that PHGs have margins of safety adequate to protect sensitive subpopulations, such as pregnant women and infants, from the harmful effects of contaminants.

8. Did the recent peer review by the University of California raise questions about the validity of the PHG? Did the three peer reviewers write reports that contradicted each other?

A: The peer review was, on balance, very supportive of OEHHA's PHG document. All three reviewers complimented OEHHA on the quality and thoroughness of its assessment. All three reviewers agreed with OEHHA's decision to use data from the Greer study (cited in the response to Question No. 7) as the basis for the PHG. All three reviewers agreed that the PHG should be set at a level most protective of susceptible populations, including pregnant women and infants. All three reviewers agreed that OEHHA should set the PHG at the level that would protect against significant disruption of iodide uptake by the thyroid gland. As explained in the response to Question No. 7, the main source of disagreement among the peer reviewers was on the margins of safety that should be applied to the Greer study's data on healthy adults to ensure the PHG protects pregnant women and infants.

In finalizing the PHG, OEHHA adjusted its margin of safety calculations in response to the peer reviewers' comments.

The purpose of the peer review is to provide advice and guidance to OEHHA in ensuring that its assessments are based on sound scientific knowledge, methods and practices. The peer reviewers are not asked to approve or reject a PHG, nor are they expected to reach a consensus. As with any governmental entity that receives input from an advisory body of experts, OEHHA is expected to carefully consider revising a draft PHG based on peer reviewers' comments. In instances when OEHHA disagrees with a peer reviewer's conclusions, OEHHA develops a written response that is publicly available when the PHG is finalized.

9. Did one of the peer reviewers recommend a perchlorate PHG of about 200 ppb?

A: No. The peer reviewer cited a finding from the Greer study that suggested a level of 180 to 220 ppb of perchlorate in drinking water would have no observable health effects on a 70 kilogram (155 pounds) person. The peer reviewer cited the finding accurately. However, the peer reviewer did not specifically address how margins of safety, if any, should be applied to calculate a PHG that protects more susceptible populations, such as pregnant women and infants. The other two peer reviewers discussed margins of safety in their reports, and recommended PHGs of 2 ppb and 18.6 ppb, respectively.

10. Should OEHHA have waited for the completion of the National Academies of Science (NAS) review of perchlorate before finalizing the PHG?

A: OEHHA was compelled to publish the PHG prior to the completion of the NAS review for the following reasons:

- OEHHA was mandated by law to publish the PHG. The Legislature, in passing SB 1822, set a deadline of January 1, 2003, for publication of the PHG. OEHHA could not meet this deadline because of a lawsuit. A court order stemming from the lawsuit resulted in a deadline of March 12, 2004, for publishing the PHG.
- The NAS is conducting an evaluation of U.S. EPA's 2002 Draft Toxicological and Risk Characterization for Perchlorate. This is an important undertaking that may help guide efforts to study the health effects of perchlorate. When that evaluation is completed, OEHHA will carefully review the NAS conclusions and will revise the PHG as necessary.

11. Why was there a court order requiring publication of the PHG by March 12, 2004?

A: In 2002, Lockheed Martin and Kerr McGee sued OEHHA over a procedural issue relating to the peer review of the then-draft PHG. The lawsuit did not raise any scientific issues. The issue in the lawsuit was whether Lockheed Martin and Kerr McGee were

legally entitled to request (and obtain) a second peer review of OEHHA's draft PHG document. The judge ruled that procedural requirements in state law required OEHHA to accept the two firms' request for a second peer review. The order issued by the judge required OEHHA to finalize the PHG within 60 days of the completion of the second peer review, which was delivered to OEHHA on January 12, 2004.

12. Could perchlorate in drinking water cause cancer?

A: No. Perchlorate does not pose a known cancer risk to the public.

13. Is the PHG effective immediately?

A: Yes. However, the PHG is a drinking water goal only. The State's drinking water providers are not required to take action simply because the PHG has been published. As explained in the response to Question No. 2, DHS will use the PHG to establish the Maximum Contaminant Level (MCL), which will be the enforceable regulatory requirement for drinking water systems.

14. Must drinking water suppliers meet the PHG?

A: The PHG is a drinking water goal only. There will be no consequences to drinking water providers if they cannot reduce perchlorate levels in their water to meet the PHG. Drinking water suppliers will have to comply with the MCL when it is adopted. As discussed in Question No. 16, drinking water suppliers are already monitoring for perchlorate, and very few suppliers are serving water with perchlorate levels exceeding 4 ppb.

Once the MCL is established, systems exceeding the MCL are required to notify DHS and the public and take steps to immediately come back into compliance. If the MCL is exceeded by 10 times the water system, the water system is required to remove the source from service.

15. How does the PHG compare to advisory levels adopted by other states and the federal government?

A: A provisional federal guideline developed in 1992 suggests concentrations of perchlorate in water ranging from 4 to 18 ppb would not pose a risk to human health. In 2002, U.S. EPA released a draft health-protective guideline for perchlorate equivalent to a concentration of 1 ppb for drinking water. The NAS review discussed in previous questions is, in fact, a peer review of the U.S. EPA document that developed this guideline. Advisory levels for perchlorate in other states are: Arizona, 14 ppb; Nevada, 18 ppb; New York, 5 to 18 ppb; Texas, 4 to 10 ppb; Massachusetts, 1 ppb; Maryland, 1 ppb; New Mexico, 1 ppb.

16. Does perchlorate make California's drinking water systems unsafe?

A: No. Drinking water suppliers are monitoring their water for perchlorate as required by DHS, which has the authority to order suppliers not to provide water with unsafe levels of perchlorate. Since January 2002, DHS has had an “action level” (an advisory level for contaminants for which there is no drinking water standard) of 4 ppb for perchlorate. (DHS has aligned the action level to the 6 ppb PHG.) While perchlorate has been detected at or above the 4 ppb level in almost 350 drinking water sources (primarily ground water wells) statewide, drinking water providers have taken action to ensure that very few drinking water systems are providing water with perchlorate levels exceeding 4 ppb. Perchlorate levels in the Colorado River, a major source of drinking water for Southern California, currently range from 4 to 6 ppb (U.S. EPA, Region 9, Perchlorate Monitoring Results, Henderson, Nevada to the Lower Colorado River, December 2003 report), which are within the level of the PHG. The water is blended with water from other sources to reduce perchlorate levels prior to delivery to the public.

17. Will the PHG cause perchlorate to be subject to Proposition 65?

A: No. The development of a PHG for a chemical does not trigger a requirement for that chemical to be subject to Proposition 65, the 1986 voter-approved law that requires California to maintain a list of chemicals known to cause cancer, birth defects or other reproductive harm. Perchlorate currently is under consideration for addition to the Proposition 65 list of chemicals that cause reproductive health effects. An independent scientific panel administered by OEHHA will decide whether to add perchlorate to the Proposition 65 list, but this will not take place earlier than 2005. Proposition 65 contains very specific criteria for the listing of chemicals and is separate from California’s drinking water laws regarding PHGs and MCLs.

18. Where is the perchlorate in drinking water coming from?

A: Perchlorate salts are primarily used as an oxygen-adding component in solid rocket fuel, missiles, explosives, munitions, pyrotechnics, military countermeasures, highway safety flares, fireworks, matches and in electroplating. Over 90 percent of all the perchlorate salts manufactured in United States have been used in the manufacture of solid rocket fuel. Past product utilization and outmoded disposal methods are believed to have allowed for large releases of perchlorate into the environment that has made its way into groundwater aquifers that are used for drinking water.

19. What is being done about perchlorate contamination?

A: As noted in the answer to Question No. 16, drinking water suppliers have taken action to address contaminated sources. Some suppliers have removed sources from service, while others are using wellhead treatment technologies to remove perchlorate from the drinking water sources. In addition, some systems are using blending to reduce perchlorate levels in water prior to delivery to the public.

The Regional Water Quality Control Boards (RWQCBs) and the Department of Toxic Substances Control (DTSC) have been focusing their efforts on investigating industrial facilities, military sites and other possible sources in areas where perchlorate has been detected in municipal water supply wells. Other sites are in earlier stages of investigation.

20. How much will it cost to clean up the perchlorate contamination, and who will pay for it?

A: We do not yet know what the total cost of cleanup will be. The RWQCBs and DTSC are still investigating the possible sources of the contamination. Generally speaking, those who polluted the environment are responsible for paying for its cleanup. California is coordinating its efforts with the 32 other states that have found perchlorate in their drinking water, and is pursuing cooperative efforts with the U.S. EPA, the Department of Defense, the Department of Energy, the National Aeronautics and Space Administration, the aerospace industry, and others to better assess the scope of the problem and ways to address it. The DHS, when establishing the MCL, will take into account the cost to water suppliers and their customers to clean up perchlorate contamination in drinking water, while placing primary emphasis on public health.

21. Where can I get more information?

A: The PHG document, including OEHHA's responses to comments received during the peer reviews and public comment periods, will be available on March 12, 2004, in compliance with the court order. It will be available for download from OEHHA's Web site at www.oehha.ca.gov. Further information on PHGs can be obtained by contacting OEHHA at (916) 324-7572, or by mail at P.O. Box 4010, Sacramento, CA 95812-4010.

Information about the DHS process for establishing a drinking water standard, or MCL, for perchlorate, is available at www.dhs.ca.gov, or by contacting DHS at (916) 440-7660.